

The Public's Health and the Law in the 21st Century: Law at the Intersection of Civilian and Military Public Health Practice

John A. Casciotti
Office of the General Counsel
Department of Defense
June 2006

Public Health Law Intersection

Outline:

- Basic Facts on Military Health System
- Basic Concepts at the Intersection
- Top 10 Issues in Military Public Health Law
- Recap: Competing Interests, Common Causes

Basic Facts: Military Health System

[FY-06: \$38 Billion]

Maintain a Fit and Healthy Force

- 1.4 million Active Duty members
- 1.2 Reserve Component members
 - Deployed worldwide
 - "Public Health Law"

Direct Care System

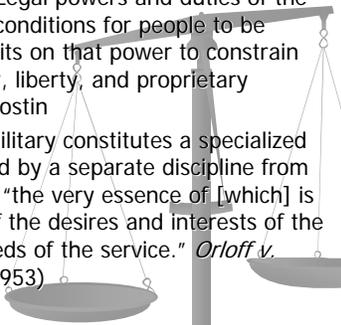
- 70 Hospitals, 411 clinics
- 130,000 "employees"
- 9.1 million eligible beneficiaries
 - "Health Care Law"

Purchased Care System

- CHAMPUS/TRICARE
- 700,000 inpatient admissions
- 100 million claims paid
- "Health Reimbursement Law"

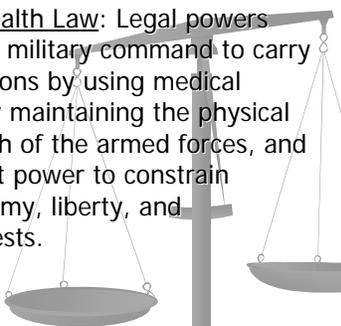
Basic Concepts

- **Public Health law:** "Legal powers and duties of the state to assure the conditions for people to be healthy, and the limits on that power to constrain individual autonomy, liberty, and proprietary interests." - Prof. Gostin
- **Military law:** "The military constitutes a specialized community governed by a separate discipline from that of the civilian," "the very essence of [which] is the subordination of the desires and interests of the individual to the needs of the service." *Orloff v. Willoughby* (S.Ct. 1953)



Basic Concepts: A Definition

Military Public Health Law: Legal powers and duties of the military command to carry out military missions by using medical personnel and by maintaining the physical and mental health of the armed forces, and the extent of that power to constrain individual autonomy, liberty, and proprietary interests.



21st Century Intersection of Military and Civilian Public Health Law?



Top 10: Anthrax Vaccine

- Expect opposition to bioterrorism countermeasures, litigation challenges
- Injunctions in 2003 and 2004 against DoD based on perceived procedural defects by FDA in approving anthrax vaccine
- Public health consensus that anthrax vaccine is safe and effective
- What's up: health protection vs. independent validation that drug is safe and effective
- Note to self: Pay attention to FDA procedures

Top 10: BioShield FDA Emergency Use Authorization

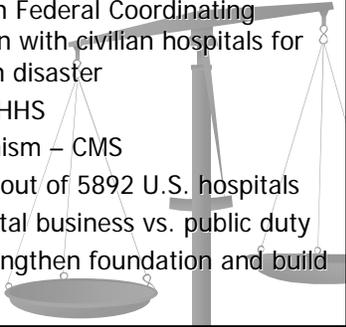
- Alternative to relying on Investigational New Drug process for emergency public health
- Anthrax postal attack highlighted need
- Research purpose vs. Public Health purpose
- Informed consent vs. Possible mandate
- Option to refuse: "to the extent practicable given the circumstances of the emergency"
- What if: Contagious disease? First responders?
- Note to self: Keep all options on the table

Top 10: Public Health Emergency Powers

- DoD Directive 6200.2, "Emergency Health Powers on Military Installations," 2003
- Modeled after Model State Emergency Public Health Act
- Public Health Emergency Officer coordinate with State and CDC
- What's up: Emergency powers vs. Autonomy
- Note to self: Plan together

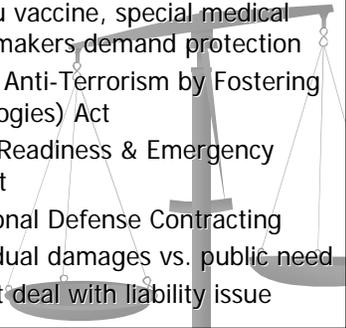
Top 10: National Disaster Medical System Hospital Network

- DoD and DVA run Federal Coordinating Centers for liaison with civilian hospitals for military or civilian disaster
- HHS to FEMA to HHS
- Payment mechanism – CMS
- MOUs with 1656 out of 5892 U.S. hospitals
- What's up: Hospital business vs. public duty
- Note to self: Strengthen foundation and build



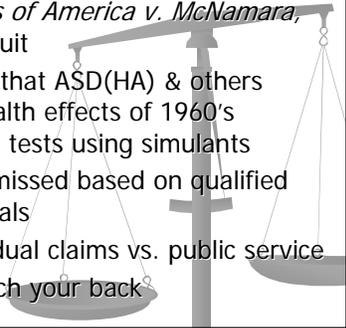
Top 10: Liability and Indemnification for Drug Makers

- Ghost of swine flu vaccine, special medical countermeasure makers demand protection
- SAFETY (Support Anti-Terrorism by Fostering Effective Technologies) Act
- PREP Act (Public Readiness & Emergency Preparedness) Act
- PL 85-804 – National Defense Contracting
- What's up: individual damages vs. public need
- Note to self: Must deal with liability issue



Top 10: Personal Liability for Public Health Officials

- *Vietnam Veterans of America v. McNamara*, pending D.C. Circuit
- *Bivens* complaint that ASD(HA) & others covered up of health effects of 1960's biological warfare tests using simulants
- District Court dismissed based on qualified immunity of officials
- What's up: individual claims vs. public service
- Note to self: Watch your back



Top 10: Detainee Health Care

- Need better intelligence to win War on Terror
- Must interrogate captured enemy combatants
- Medical support for interrogations, like FBI profilers: behavioral science consultants
- Law of war (not *Miranda*), but all is not fair
- Detainee Treatment Act: prohibits "cruel, inhuman or degrading treatment"
- Achieve mission vs. legal & ethical standards
- Note to self: Must do both

Top 10: Research vs. Public Health

- Research = systematic investigation designed to contribute to generalizable knowledge
- 10 USC 1074f: pre and post deployment assessments: systematic and generalizable
- Unclear if CDC and OHRP on the same page
- DoD applies Belmont Report definition: "an activity designed to test an hypothesis . . ."
- What's up: autonomy vs. public good
- Note to self: Not the time to weaken public health authorities

Top 10: HIPAA Accounting

- HIPAA allows disclosures without authorization for public health & military command purposes
- HIPAA requires accounting for each disclosure
- Command monitoring of fitness for mission assignments continuous and extensive
- Accounting very burdensome & expensive
- Request: exempt disclosures required by law
- What's up: privacy notice vs. public mission
- Note to self: "administrative simplification"

Top 10: Disease Surveillance

- Need better, faster identification of emerging infectious diseases worldwide
- Public health surveillance tools vs. In vitro diagnostic devices regulated by FDA
- Real Time Polymerase Chain Reaction (RT-PCR) for wide range of pathogens
- What's up: treatment purpose vs. surveillance
- Note to self: EUA for surveillance?

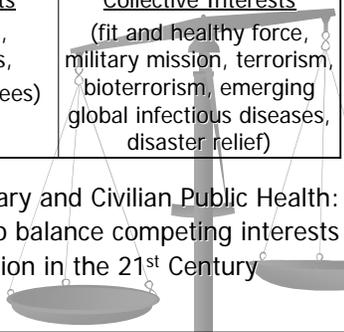


What's Up: Competing Interests

<u>Individual Interests</u> (soldiers, citizens, hospitals, patients, tort plaintiffs, detainees)	<u>Collective Interests</u> (fit and healthy force, military mission, terrorism, bioterrorism, emerging global infectious diseases, disaster relief)
--	---

Notes to self - Military and Civilian Public Health:

- Common cause to balance competing interests
- A busier intersection in the 21st Century



For More Information

- DoD:
<http://www.defenselink.mil/>
- Military Health System:
<http://www.ha.osd.mil/>
- DoD Directives:
<http://www.dtic.mil/whs/directives/>
- Military Health Law Network:
<http://www.usuhs.mil/ogc/mhln/>

